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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/723,499 | 11/25/2003 | Keith Rosiello | 350930-0201 (ZQI-129 US) | 8935 |
| 48329 7590 07/16/2009 FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610 | | | EXAMINER SORKIN, DAVID L | |
| | | | ART UNIT 1797 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/723,499 | Applicant(s) ROSIELLO ET AL. | |
| | Examiner DAVID L. SORKIN | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-18,20-30 and 32-51 is/are pending in the application.
- 4a) Of the above claim(s) 39-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-18,20-30,32-38 and 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 July 2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6, 8-18, 20-30, 32-38 and 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the recitations of "flexible bag" require that all portions of the bag be flexible including the weld rings required by claim 12 and the solid circumferential ring required by claim 5, or merely a portion of the bag be flexible.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6, 8-18, 20-30, 32-38 and 49-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. While the

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scope of the term “flexible bag” is unclear as explained above, to the extent that the term requires the bag to be made entirely of flexible material, the new limitation is considered new matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6, 8-18, 20-29, 34, 49 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Jorgensen et al. (US 2002/0107131). Regarding claims 1, 13 and 24, Jorgensen ('131) discloses a flexible bag (10, 50, 94, or 96) (as well as a centrifuge comprising the bag) comprising a substantially circular enclosure including a first side and a second side radially connected along an outer edge, the first sides defining an interior surface therebetween, each of the first and second sides having a respective central opening (such as 11 or 51) for housing a central hub, and a first mating portion positioned adjacent the central opening, along the interior surface of the first side, and extending in a direction perpendicular to the interior surface, and, in cross-section, including a raised shape (for example 100) the mating portion integrally formed (see [0043]) for mating in a cooperative arrangement with a corresponding mating portion of a hub (20,60,104) and the raised shape of opposing an interior surface of the second side (see Fig. 11). Regarding claims 2, 14, and 25, the first mating portion comprises an integrally molded radial barrier (see Figs. 1 and 11). Regarding claims 3, 9, 15, 21,

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and 26, the first mating portion comprises one or more recesses formed adjacent the opening (see especially Fig. 1). Regarding claims 4, 10, 16, 22 and 27 the first mating portion comprises one or more raised areas formed adjacent the opening (see Figs. 1 and 11). Regarding claims 5, 17 and 28, the radial barrier comprises a circumferential ring of raised material (see Figs. 1 and 11). Regarding claims 6, 18 and 29, the radial barrier comprises a circumferential recess (see Figs. 1 and 11). Regarding claims 8 and 20, each side includes a first mating portion (see Fig. 1, 3, 7 and 11). Regarding claim 11, the manner in which the bag is intended to be used is not germane to the patentability of the bag. Regarding claims 12 and 23, the bag further comprises at least one weld ring (30, 40, 70, 80, 100 or 102) having a central opening for receiving a first side of the hub and a surface positioned adjacent the first side of the bag proximate the opening of the first side. Regarding claim 34, Jorgensen ('131) discloses a method of sealing a centrifuge bag to a hub comprising providing a flexible bag (10, 50, 94 or 96) for use in centrifugal processing, wherein the bag comprises a substantially circular enclosure including a first side and a second side radially connected to the first side along an outer edge, the first and second sides defining an interior therebetween, the first and second sides each having a respective central opening (such as 11 or 51) for housing a central hub, wherein the central opening includes a first mating portion (see Figs. 1 and 11) positioned adjacent to the central opening, along the interior surface of the first side, extending in a direction perpendicular to the interior surface, in cross-section including a least one raised shape (100) with respect to the interior surface, and the first mating portion opposing an interior of the second side; providing a hub (20, 60

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or 104) having a second portion corresponding to the first mating portion, wherein the first mating portion integrally formed for mating in a cooperative arrangement with the second mating portion; and placing the hub with in the opening; and mating the first mating portion with the second mating portion (see [0043], [0050], Figs. 1-8 and 11).

Regarding claim 49, the first side is flat (see Fig. 11). Regarding claim 51, the shape is a rectangle (see Fig. 11).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. (US 2002/0107131). The method of Jorgensen was discussed above with regard to claim 34. While the verb “welding” is not expressly used by the reference, “weld rings” are extensively discussed (see [0047] and [0050]). The discussion of “weld rings” would have suggested welding, either with heat or with solvent, to one of ordinary skill in the art.

10. Claims 30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. (US 2002/0107131) in view of Schlutz (US 3,982,691). Jorgensen ('131) discloses a method of sealing a centrifuge bag to a hub comprising providing a bag (10, 50, 94 or 96) for use in centrifugal processing, wherein the bag comprises a substantially circular enclosure including a first side and a second side radially

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connected to the first side along an outer edge, the first and second sides defining an interior surface therebetween, at least one of the first and second sides having a central opening (such as 11 or 51), wherein the central opening is for housing a central hub, wherein the central opening includes a first mating portion (see Figs. 1 and 11) positioned adjacent to the central opening, along the interior of at least one of the first and second sides and extending in a direction perpendicular to the interior surface; and providing a hub (20, 60 or 104) having a second portion corresponding to the first mating portion; placing the hub within the opening; and mating the first mating portion with the second mating portion (see [0043], [0050], Figs. 1-8 and 11). Use of adhesive is not explicitly disclosed. Schlutz ('691) teaches joining components of a centrifuge bag assembly using adhesive (see col. 12, lines 1-9). It would have been obvious to one of ordinary skill in the art to have joined the portions of Jorgensen ('131) using adhesive, because, since Jorgensen ('131) explains that joining is required but does not detail exactly how, one would look to prior art methods of joining such as those of Schlutz ('691), col. 12, lines 1-9.

11. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. (US 2002/0107131). The shape being semi-circular is not clearly disclosed. However, as applicant admits on pages "[o]ne of ordinary skill in the art will recognize" that other shapes may be used.

Response to Arguments

12. Applicant argues that the weld rings of the prior art not part of the flexible bag, but part of the greater flexible bag *assembly*, while applicant at the same time requires that weld rings are part of the flexible bag itself, in for example, claim 12.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID L. SORKIN whose telephone number is (571)272-1148. The examiner can normally be reached on Mon.-Fri. 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID L. SORKIN/

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Primary Examiner, Art Unit 1797